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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,970	01/03/2001	Hideaki Nomura	081356/0156	8299
22428	7590	03/03/2004	EXAMINER	
FOLEY AND LARDNER SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			GOLLAMUDI, SHARMILA S	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 03/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/720,970

Applicant(s)

NOMURA ET AL.

Examiner

Sharmila S. Gollamudi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 6-9, 13, 14, 16-20 and 22-25 is/are pending in the application.
- 4a) Of the above claim(s) 26-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 6-9, 13, 14, 16-20 and 22-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt of Amendments to the Claims and Rule 132 Declaration received on December 4, 2003 is acknowledged. Receipt of Information Disclosure received on September 30, 2003 is acknowledged. Claim **1-2, 6-9, 13-14, 16-20, and 22-25** are pending in this application. Claims 26-29 are withdrawn. Claims 3-5, 10-12, and 15 stand cancelled.

Election/Restrictions

Newly submitted claims 26-29 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims originally presented are directed towards a powder preparation and new claims 26-29 are directed towards a method of enhancing absorption, which is a different invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 26-29 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Response to Amendment

The Declaration under 37 CFR 1.132 filed December 4, 2003 is insufficient to overcome the rejections as set forth in the last Office action because: Firstly, the examiner points out that the unexpected results are not comparative with the closest prior art, i.e. Cumming's composition compared to instant composition or Norling's composition compared to instant composition. The applicant merely compares different polymers and the effect of transmission of the drug, not the compositions. However, the

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prior art clearly teaches instant acrylate polymers, i.e. Eudragit polymers, specifically E-100. Secondly, the examiner points out that the Declaration utilizes a specific concentration, which are not reflected in the independent claim; thus the claims are not commensurate in scope.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 22-23 contains the trademark/trade name Eudragit E copolymer and Eudragit E100. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe an acrylate copolymer and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 7, 9, 13-14, 16-17, 19-20, and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cumming et al (6,153,220).

Cumming et al teach a taste-masked formulation containing a cationic copolymer (Eudragit E 100) and a drug in powder form. See Abstract and examples. Cumming teaches drugs such as peptides, proteins, and hormones in the composition. See column 3, lines 9-10. Several ratios are taught such as 1:1, 1:2, 1:10, etc. See Table 1. The composition may include conventional excipients (adjuvant). See examples.

Cummings does not exemplify the instant drugs.

It is deemed obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance provided by Cumming and utilize the instant drugs in the composition. One would be motivated to do so since Cumming teaches the

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suitability of proteins, peptides, and hormones as the active agent. Therefore, one would be motivated to utilize a particular drug depending on the symptom to be treated.

Response to Arguments

Applicant argues that Cumming does not address the problems associated with administering high molecular weight drugs into the mucosa. It is argued that Cumming does not address utilizing a methacrylate-based preparation for improving transmission of a high molecular drug through the mucosa.

Applicant's arguments have been fully considered but they are not persuasive. Firstly, the examiner again points out that the claims are directed to a powder preparation. Thus, in product claims the intended use of the product does not hold patentable weight; patentability lies with the product itself. Therefore, Cummings does not have to teach the instant administration. Secondly, in product claims, the prior art does not have to have the same reason for utilizing a certain polymer as the applicant since patentability lies with the product. Clearly, Cumming teaches the use of the instant polymer in the compositions and thus reads on the instant claims. In regards to the method claims, as established above, the new claims have been withdrawn.

Applicant argues that the exemplary drugs in the prior art are low molecular weight drugs.

Applicant's arguments have been fully considered but they are not persuasive. On page 6, of instant specification defines a high molecular weight as: "A medicine of high molecular weight" used in the invention refers to a bioactive peptide or protein; antibody, vaccine, antigen or the like. Clearly, Cumming teaches instant drugs on

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column 3, lines 5-26. Secondly, disclosed examples, i.e. the use of low molecular drugs, do not constitute a teaching away from the broader disclosure, i.e. the use of proteins, peptides, etc.

Applicant argues that Cumming's composition is directed towards taste masking and teaches the copolymer in greater quantities than the drug. In contrast the instant invention requires the ratio of cationic copolymer to drug to be less than 2:1.

Applicant's arguments have been fully considered but they are not persuasive. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a 2:1 ratio) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In instant case, independent claim 1 does not recite this ratio.

In regards to claim 13, the claims merely recites that the ratio is less than 2:1. Cumming clearly teaches a composition with the ratio of 2:1. It should be noted that the claims are rejected under 103 and it is the examiner's position that manipulation of amounts does not necessitate a patentable invention. Firstly, "less" is not defined. For instance, if the prior art taught the polymer to drug to be 60:30 (2:1 ratio) and the applicant tweaked the amounts to be 59.99:30.01, although the ratio is less than 2:1, it is in a negligible amount and falls within the obvious scope of the prior art.

Claims 1-2, 6-9, 13-14, 16-20, 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Norling et al (5,958,458).

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Norling et al disclose a particulate formulation in the form of coated cores. The cores comprise active agents such as hormones, peptides, calcitonin, insulin, colony stimulating factors, theophylline (haptan), etc. See column 7 and 8. The cores additionally contain a coating such as a film coating based on one or more materials such as HPMC, Eudragit E or modified release coat such as Eudragit RL or RS, or a combination of coatings in instant amount. See column 9, line 43 to column 10, line 20 and example 10. Excipients are taught, especially binding agents such as HPMC. See column 13, lines 40-65. Inert carriers are taught on column 5, lines 9-15. Nasal formulations are taught on column 14, lines 44-65.

Norling does not exemplify instant drugs.

It is deemed obvious of one of ordinary skill in the art at the time the invention was made to look to the guidance of Norling et al and utilize instant drug. One would be motivated to do so since Norling teaches insulin, calcitonin, GCSF, and peptides are suitable as active agents in the particulate formulation. Therefore, one would be motivated to utilize a particular drug depending on the symptom to be treated.

Response to Arguments

Applicant argues that Norling teaches a formulation in the form of coated cores. Applicant argues that claim 1 recites the phrase "consisting essentially of" overcomes the Norling's "inert carrier".

Applicant's arguments have been fully considered but they are not persuasive. As noted by applicant, Norling teaches an *inert* carrier and "consisting essentially language" only excludes components that affect the basic composition. The definition of

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inert is "deficient in active properties." Thus, inert materials do not change the basic property of a product since it has no affect on the composition. Further, the examiner points out that claims 19-20 recite the inclusion of an adjuvant. Thus, Norling's carrier falls under the term of adjuvant, which defined as "something that enhances the effectiveness of medical treatment."

Applicant argues unexpected results in the specification.

Applicant's arguments have been fully considered but they are not persuasive. The examiner points out that unexpected results should be compared to the closest prior art, i.e. Norling's composition to instant composition. Further, the declaration demonstrates that the instant acrylate polymer is superior to other polymers. This is not an unexpected results since Norling clearly utilizes acrylate polymer coats in the examples.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Norling et al (5,958,458) in view of JP 406065090.

Norling et al disclose a particulate formulation in the form of coated cores. The cores comprise active agents such as hormones, peptides, calcitonin, insulin, colony stimulating factors, theophylline (haptent), etc. See column 7 and 8. The cores additionally contain a coating such as a film coating based on one or more materials such as HPMC, Eudragit E or modified release coat such as Eudragit RL or RS, or a combination of coatings in instant amount. See column 9, line 43 to column 10, line 20 and example 10. Excipients are taught, especially binding agents such as HPMC. See

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column 13, lines 40-65. Inert carriers are taught on column 5, lines 9-15. Nasal formulations are taught on column 14, lines 44-65.

Norling et al do not specify G-CSF.

JP teaches G-CSF in a nasal formulation for curing leucopenia.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Norling et al and JP and utilize G-CSF. One would be motivated to do so since JP teaches that the instant active treats leucopenia. Further, one would be motivated to do so with the expectation of similar results since Norling et al teach the suitability of CSF in the formulation. Therefore, one would be motivated to utilize G-CSF in the formulation to treat leucopenia.

Response to Arguments

Applicant argues for the reasons that Norling teaches an inert carrier, thus the claims are not obvious since claims exclude the inert carrier. Further, applicant argues unexpected results.

Applicant's arguments have been fully considered but they are not persuasive. The arguments pertaining to Norling and the unexpected results have been addressed above.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Norling et al (5,958,458) in view of Stanton et al (5,807,552).

Norling et al disclose a particulate formulation in the form of coated cores. The cores comprise active agents such as hormones, peptides, calcitonin, insulin, colony stimulating factors, theophylline (hapten), etc. See column 7 and 8. The cores

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additionally contain a coating such as a film coating based on one or more materials such as HPMC, Eudragit E or modified release coat such as Eudragit RL or RS, or a combination of coatings in instant amount. See column 9, line 43 to column 10, line 20 and example 10. Excipients are taught, especially binding agents such as HPMC. See column 13, lines 40-65. Inert carriers are taught on column 5, lines 9-15. Nasal formulations are taught on column 14, lines 44-65.

Norling et al do not specify a protein that is conjugated to a hapten.

Stanton et al teach the use of hapten-carrier (protein) molecules for use in human and animal prophylaxis. Stanton teaches the hapten-carrier molecules illicit immune response and functions as vaccine (col. 3, lines 10-40).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Norling et al and Stanton et al and utilize a hapten conjugated protein. One would be motivated to do so since hapten-carrier (protein) molecules function as a vaccine as taught by Stanton et al. Therefore, one would be motivated to incorporate a specific medicine depending on the symptoms to be treated or desired affect.

Response to Arguments

Applicant argues that since Norling teaches an inert carrier that claims are not obvious. Applicant argues there is not motivation to exclude the inert carrier.

Applicant's arguments have been fully considered but they are not persuasive. The arguments pertaining to Norling have been addressed above. Again the examiner points out that the consisting essentially does not exclude an **inert** carrier. Further, the

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applicant clearly allows for an adjuvant in the dependent claims and thus the arguments contradict the invention.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-242-0614. The examiner can normally be reached on M-F (8:00-5:00) with every other Friday off.

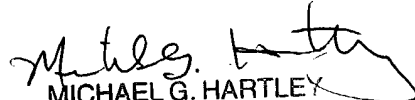
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SSG


February 26, 2004


MICHAEL G. HARTLEY
PRIMARY EXAMINER